DRAFT

Refractec®

ViewPoint™ CK System

PROFESSIONAL USE INFORMATION MANUAL FOR TREATMENT OF PRESBYOPIC EMMETROPES AND HYPEROPES TO IMPROVE NEAR VISION UTILIZING CONDUCTIVE KERATOPLASTY® (CK®)

PHYSICIAN'S REFERENCE GUIDE

For the temporary induction of myopia (-1.00 D to -2.00 D) to improve near vision in the non-dominant eye of presbyopic hyperopes or presbyopic emmetropes, via spherical hyperopic treatment of 1.00 to 2.25 D, in patients:

- 40 years of age or greater;
- with a documented stability of refraction for the prior 12 months, as demonstrated by a change of < 0.50D in spherical and cylindrical components of the manifest refraction;
- with ≤ 0.75 D of cycloplegic refractive cylinder; and
- with a successful preoperative trial of monovision or history of monovision wear (i.e., dominant eye corrected for distance vision and non-dominant eye corrected for near vision).

CAUTION

Restricted Device: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner. U.S. Federal Law restricts the use of this device to practitioners who have been trained in its operation and who have experience in the surgical management and treatment of refractive errors.

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I. GENERAL WARNINGS

"WARNING!"

Identifies conditions or practices that could result in damage to equipment or other property, personal injury or loss of life.

WARNINGS:

WARNING! This document provides information concerning the intended clinical use of the Refractec ViewPoint™ CK System. For complete information concerning system components, safety instructions, installation, maintenance, and troubleshooting, refer to the Refractec ViewPoint™ CK System *Operator's Manual.*

WARNING! Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient and/or user complications.

WARNING! Any adjustments to controls or calibration other than those specified herein may result in damage or injury to the patient or the user.

WARNING! Never operate the device in the presence of flammable anesthetics or other volatile substances, such as alcohol.

WARNING! All patients must be given the opportunity to read and understand the Patient Information Booklet, and to have all of their questions answered to their satisfaction before giving consent to the Conductive Keratoplasty® (CK®) procedure or the use of the Refractec ViewPoint™ CK System.

II. INTRODUCTION

The ViewPoint™ CK System is an instrument designed to perform Conductive Keratoplasty® (CK®). CK® can be used for the temporary induction of myopia (-1.00 D to – 2.00 D) in the non-dominant eye to improve near vision (monovision) in presbyopic hyperopes or presbyopic emmetropes.

CK® is performed utilizing the ViewPoint™ CK System to create monovision . The information provided in this reference guide is supplemental and provides specific details regarding the use of the ViewPoint™ CK System to improve near vision.

Conductive Keratoplasty® utilizes low energy, delivered directly into the corneal stroma through a handpiece and Keratoplast™ Tip, to effect refractive change in the cornea. As a result of conducting a controlled amount of radiofrequency (RF) energy into the corneal stroma, the desired collagen shrinkage temperature is achieved. The peripheral application of this treatment, in a predetermined pattern, creates a band of tightening and results in a steepening of the central cornea (Figure 1). This steepening results in the desired refractive effect.

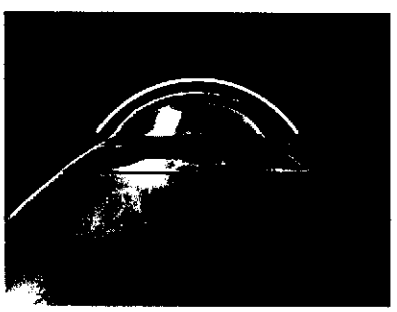

Figure 1

Conductive Keratoplasty®

The CK® procedure increases the curvature of the cornea to improve near vision (myopic endpoint in one eye).

III. DEVICE DESCRIPTION

The ViewPoint™ CK System (Figure 2) used to perform the CK® procedure consists of the following components:

- Radiofrequency energy-generating console
- Reusable corneal marker
- Reusable lid speculum (Figure 3) with cable and connector
- Reusable hand-held, pen-shaped handpiece with cable and connector
- Instrument holder
- Power cable
- Footpedal
- Disposable Keratoplast™ Tip
- Patient treatment card

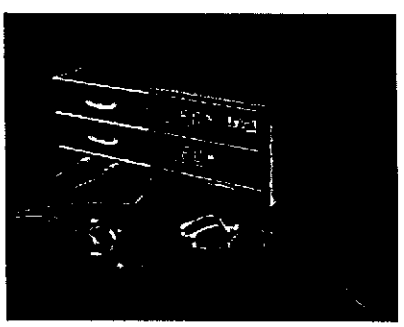

Figure 2
ViewPoint™ CK System

Figure 3
CK® Lid Specula
Lancaster type (top)
Barraquer type (bottom)

ViewPoint™ CK System Console

A patient treatment card is inserted into the console to activate the system. The energy level is set at 60% power (0.6W) with a treatment time of 0.6 seconds. An AC powered, portable, low power, energy source provides regulated radiofrequency energy through the handpiece to the Keratoplast™ Tip.

Handpiece

The handpiece is a small hand-held, pen-shaped, reusable Titanium instrument attached by a removable cable and connector to the console. The radiofrequency energy is delivered by means of the Keratoplast™ Tip, which attaches to the handpiece.

Keratoplast™ Tip

A sterile, disposable, stainless steel, Keratoplast™ Tip (Figure 4), 90 microns in diameter and 450 microns long, that delivers radiofrequency energy directly to the corneal stroma, is attached to the handpiece. The Keratoplast™ Tip has a proximal bend of 45° and a distal bend of 90° to allow access to the cornea over the patient's brow and nasal regions. A plastic stop at the very distal portion of the stainless steel tip assures correct depth of penetration. The Keratoplast™ Tip must not be used on fellow eyes or subsequent patients.

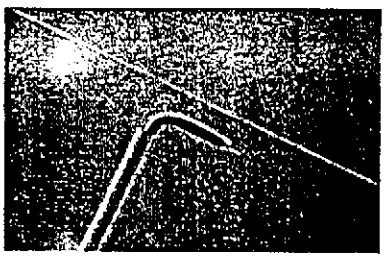

Figure 4

CK® Keratoplast™ Tip

Lid Speculum

The lid speculum (Figure 3 above) serves as the return (dispersive) electrode for the radiofrequency energy being delivered through the Keratoplast™ Tip. Three types of specula are offered: Barraquer, Cook, and Lancaster. The Barraquer is a small, malleable wire-speculum; the Cook is a small locking speculum; and the Lancaster is a large locking speculum. The Lancaster and Cook lid specula were not used in the clinical investigation of the device.

Footpedal

The footpedal attaches to the console and controls the release of radiofrequency energy.

Patient Treatment Card

A patient treatment card is inserted into the console to activate the system.

Safety Features

The ViewPoint™ CK System has numerous safety features to assure proper operation. The ViewPoint™ CK System includes safety checks at start-up and monitors output during treatment.

Software

The ViewPoint™ CK System software controls the user interface, and provides the user with system diagnostics and information codes in the event of a device anomaly. Additionally, the software saves all information codes on to the patient treatment card to assist in the diagnosis of technical issues.

Note: Additional details regarding operation of this device can be found in the Refractec ViewPoint™ CK System Operator's Manual.

IV. INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE EVENTS

INDICATIONS FOR USE

The ViewPoint™ CK System is indicated for the temporary induction of myopia (-1.00 D to -2.00 D) to improve near vision in the non-dominant eye of presbyopic hyperopes or presbyopic emmetropes, via spherical hyperopic treatment of 1.00 to 2.25 D, in patients:

- 40 years of age or greater;
- with a documented stability of refraction for the prior 12 months, as demonstrated by a change of < 0.50 D in spherical and cylindrical components of the manifest refraction;
- with ≤0.75 D of cycloplegic refractive cylinder; and
- with a successful preoperative trial of monovision or history of monovision wear (i.e., dominant eye corrected for distance vision and non-dominant eye corrected for near vision).

NOTE: Refer to the preceding General Warnings section of this *Physician's Reference Guide*, in addition to the warnings and precautions found in this section.

CONTRAINDICATIONS

The Refractec ViewPoint™ CK System / Conductive Keratoplasty® (CK®) procedure should not be used in:

- Patients who are pregnant or lactating.
- Patients with keratoconus or other ectatic diseases.
- Patients who have diabetes, diagnosed autoimmune disease, connective tissue disease, or clinically significant atopic syndrome.
- Patients who are being treated with chronic systemic corticosteroid or other immunosuppressive therapy that may affect wound healing, and any immunocompromised patients.
- Patients with implantable electrical devices (pacemakers, defibrillators, cochlear implants, etc).
- Patients with nystagmus or other condition that prevents a steady gaze, which is required during surgery.

WARNINGS

The Refractec ViewPoint™ CK System / Conductive Keratoplasty® (CK®) procedure is NOT recommended in:

- Patients with a history of keloid formation.
- Patients with a history of Herpes zoster or Herpes simplex keratitis.
- Patients with intractable keratoconjunctivitis sicca.
- Patients with narrow angles.
- Patients who have had previous strabismus surgery or are likely to develop strabismus following the CK® procedure.
- Patients with unstable refraction over the year prior to examination.
- Patients with a peripheral pachymetry reading, measured at the 6 mm optical zone, of less than 560 microns.
- Patients who have not demonstrated success in a monovision trial with contact lenses or spectacles.

Patients must refrain from wearing contact lenses 2 to 3 weeks before their eye exam (2 weeks prior for soft; 3 weeks prior for hard or gas permeable lenses). Failure to do so may produce poor surgical results.

CK® may induce variations of vision in the early post-treatment period, which may necessitate temporary spectacle correction for tasks such as driving.

PRECAUTIONS

Specific training from Refractec, Inc. is required before anyone is qualified to operate the Refractec ViewPoint™ CK System. Read and understand this manual and the Operator's Manual prior to operating the system.

The safety and effectiveness of the ViewPoint™ CK System / Conductive Keratoplasty® (CK®) procedure have NOT been established in:

- Patients with progressive hyperopia, ocular disease, corneal abnormality, or trauma in the treatment area.
- Patients who have had prior intraocular surgery, corneal surgery, or incisional keratotomy. There are no data on eyes with prior refractive surgery or other ophthalmic surgery.
- Patients with a history of glaucoma, IOP > 21 mmHg, or steroid response IOP elevation.
- Patients under 40 years of age.
- Patients requiring greater than -2.00 D of induced myopia to achieve acceptable near vision. Since the therapeutic goal of the Conductive Keratoplasty® procedure for monovision is to provide patients with functional near vision while also maintaining a clinically acceptable level of anisometropia, myopia outside of the range evaluated in the clinical trial (-1.00 D to -2.00 D) should not be induced.
- Patients with greater than 0.75 D of refractive astigmatism.
- Eyes previously treated with other refractive surgical procedures.
- Patients with more than 0.50 D difference between preoperative manifest refraction spherical equivalent (MRSE) and cycloplegic refraction spherical equivalent (CRSE).
- Patients with less than 20/25 BSCVA pre-operatively.
- Retreatments (NOTE: Suitability for future refractive procedures by any modality is unknown).
- CK® treatments performed at the slit lamp. All CK® treatments in the PMA clinical trial were performed supine at an operating microscope.
- Additional treatment spots added intraoperatively for the management of induced cylinder.
- Calculation of intraocular lens power with current formulae, and outcome of cataract surgery.

- Eyes requiring < 1.00 D of treatment, because there were an insufficient number of eyes studied in the clinical trial to demonstrate safety and effectiveness.
- Eyes requiring > 2.25 D of treatment, in particular, because effectiveness in the clinical trial was significantly below that of the approved indication.

There is no data available regarding the safety and effectiveness of other refractive procedures performed after CK®.

ADVERSE EVENTS

Adverse events, complications, and ocular findings reported for all eyes in the U.S. clinical studies for the Refractec ViewPoint™ CK System / Conductive Keratoplasty® (CK®) procedure for the improvement of near vision are summarized in Table 1.

Table 1
Adverse Event Summary
Eyes Treated for Near

	Month 1*		Month 3		Month 6		Month 9		Month 12	
Late onset of haze beyond 6 months with loss of 2 lines (10 letters) or more BSCVA	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Decr. in BSCVA of > 10 letters not due to irreg. astig. as shown by hard contact lens refr., at 6 mo	0/150	0%	0/148	0%	1/146	1%	0/94	0%	0/77	0%
Any corneal epithelial defect involving the keratectomy site at 1 month or later	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Corneal infiltrate or ulcer	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Corneal edema at 1 month or later	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Corneal perforation	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Corneal microbial infection	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Corneal decompensation	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Corneal scar in visual axis	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Uncontrolled IOP with increase of > 5 mm Hg above baseline and any reading above 25 mm Hg	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
IOP >25 mm Hg	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Intraocular infection	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Hypopyon	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Hyphema	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Onset of cataract unrelated to age, systemic disease, or trauma	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Retinal detachment	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Retinal vascular accidents	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Secondary surgical intervention other than CK treatment	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Death	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Other	1/150	1%	0/148	0%	0/146	0%	1/94	1%	1/77	1%
Not reported	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%

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* Includes adverse events reported from 1 day through 1 month postop.

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As shown in Table 1 above, no serious or sight-threatening adverse events have been reported to date for the study population. A total of four adverse events had been reported at the time of database closure. One patient reported the onset of Type 2 diabetes at 12 months, and another patient was diagnosed with multiple sclerosis at 9 months. Mild iritis at day 7 was reported in one eye of one patient, and this resolved uneventfully and without sequelae. A loss in best distance corrected visual acuity of more than 2 lines, from 20/16 to 20/32, was reported at 6 months in one eye, which had preoperative BCVA of 20/20 or better. The source documentation for this visit noted that this measurement was a possible technician error. At the 9 month visit, best corrected distance visual acuity had returned to 20/16.

V. CLINICAL STUDY

INTRODUCTION

A prospective, multi-center clinical study was conducted to evaluate the safety and efficacy of the Refractec ViewPoint™ CK System when used to improve near vision with the Conductive Keratoplasty® (CK®) procedure. The ViewPoint™ CK System is an instrument designed to perform Conductive Keratoplasty® (CK®). CK® has been previously approved (PMA P010018) for the temporary spherical treatment of patients with previously untreated hyperopia between 0.75 and 3.00 diopters.

CK® can also be used for the temporary induction of myopia (-1.00 D to –2.00 D) in the non-dominant eye to improve near vision (monovision) in presbyopic hyperopes or presbyopic emmetropes.

Enrollment in the clinical study was limited to patients who:

- Required a presbyopic add of +1.00 to +2.00 D, with either a documented history of successful contact lens monovision or successful completion of contact lens monovision trial.
- Had +2.00 D to plano (+0.50 to -0.50 D) cycloplegic spherical equivalent, with ≤ 0.75 D refractive cycloplegic astigmatism (cylinder).
- Discontinued using hard or rigid gas permeable contact lenses for at least 3 weeks and discontinued using soft contact lenses for at least 2 weeks prior to the preoperative evaluation in the eye to be treated.
- Had an average peripheral pachymetry reading of at least 560 microns.
- For hard contact lens wearers – had 2 central keratometry readings and 2 manifest refractions taken at least one week apart, the last of which did not differ from the previous values by more than 0.50 D in either meridian; mires were regular in the eye to be treated.
- Had distance visual acuity correctable to at least 20/40 in both eyes and near visual acuity correctable to at least J3 in the non-dominant eye.
- Were at least 40 years of age.
- Were willing and able to return for scheduled follow-up examinations for 24 months after surgery.
- Provided written informed consent.

Patients with the following conditions were excluded from the study:

- Spherical equivalent manifest refraction and spherical equivalent cycloplegic refraction with a difference of more than 0.50 D.
- Previous strabismus surgery, or who would have been likely to develop strabismus following the CK® procedure.
- Anterior segment pathology, including cataracts (in the operative eye).
- Any corneal abnormality or uncontrolled eyelid disease (in the operative eye).
- Ophthalmoscopic signs of progressive or unstable refractive error (in the operative eye).
- Distorted or unclear corneal mires.
- Blind in the fellow eye.
- Previous intraocular or corneal surgery.
- History of herpes zoster or herpes simplex keratitis.
- History of steroid-responsive rise in IOP, glaucoma, or preoperative IOP > 21 mmHg.
- At risk for angle closure or with a potentially occludable angle.
- Diabetes, diagnosed autoimmune disease, connective tissue disease, or clinically significant atopic syndrome.
- Chronic systemic corticosteroid or other immunosuppressive therapy, and any immunocompromised patients.
- Using ophthalmic medication(s) other than artificial tears for treatment of any ocular pathology.
- Using systemic medications with significant ocular side effects.
- History of keloid formation.
- Intractable keratoconjunctivitis sicca.
- Pregnant, planning to be pregnant, or lactating during the course of the study.
- Known sensitivity to planned study concomitant medications.
- Participating in any other ophthalmic drug or device clinical trial during the time of this clinical investigation.

DEMOGRAPHICS

Table 2
Demographics

		Near Eyes 150 Eyes of 150 Subjects	Distance Eyes 38 Eyes of 38 Subjects	All Eyes 188 Eyes of 150 Subjects
Gender	Male	58 39%	13 34%	58 39%
	Female	92 61%	25 66%	92 61%
Race	Caucasian	144 96%	37 97%	144 96%
	Black	1 1%	0 0%	1 1%
	Asian	1 1%	1 3%	1 1%
	Other	4 3%	0 0%	4 3%
Eye	Left	83 55%	16 42%	99 53%
	Right	67 45%	22 58%	89 47%
Age (yrs)	N	150	38	150
	Mean	52.9	54.1	52.9
	Standard Deviation	4.80	4.77	4.80
	Median	52.0	53.8	52.0
	Range	43.7,70.8	43.7,61.3	43.7,70.8
Range of Intended Correction	N	150	38	
	Mean	2.03	1.23	
	Standard Deviation	0.625	0.367	
	Median	2.00	1.25	
	Range	0.75,3.00	0.75,2.00	
Range of Target	N	150	38	
	Mean	-1.47	0.00	
	Standard Deviation	0.356	0.000	
	Median	-1.25	0.00	
	Range	-2.25,-1.00	0.00,0.00	

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Demographic information and baseline characteristics of the eyes treated for near in this study population (150 eyes of 150 subjects) are summarized in Table 2. As shown in Table 2, of the 150 enrolled subjects, 92 (61%) were female and 58 (39%) were male, with a mean age of 52.9 years (SD 4.80, range 43.7 – 70.8 years). The majority of the subjects were Caucasian (144/150 or 96%); 1% of the study population was Black, 1% Asian, and the remaining 3% of subjects were identified as Hispanic and Egyptian or other race. The mean intended correction for near eyes was 2.03 D (SD 0.625, range 0.75 – 3.00 D).

BASELINE PARAMETERS

Table 3
Preoperative Refractive Parameters

		Near Eyes		Distance Eyes	
Spherical Equivalent (MRSE) *	-0.50 to -0.125 D	19	13%	0	0%
	0.0-0.99 D	99	66%	12	32%
	1.0-2.00 D	32	21%	26	68%
	Total	150	100%	38	100%
Cylinder (manifest)	0.00 D	53	35%	10	26%
	-0.25 D	27	18%	7	18%
	-0.50 D	45	30%	18	47%
	-0.75 D	25	17%	3	8%
	-1.00 D	0	0%	0	0%
	Total	150	100%	38	100%
Spherical Equivalent (CRSE) *	-0.50 to -0.125 D	17	11%	0	0%
	0.0-0.99 D	92	61%	9	24%
	1.0-2.00 D	41	27%	29	76%
	Total	150	100%	38	100%
Cylinder (cycloplegic)	0.00 D	52	35%	11	29%
	-0.25 D	30	20%	7	18%
	-0.50 D	41	27%	15	39%
	-0.75 D	27	18%	4	11%
	-1.00 D	0	0%	1	3%
	Total	150	100%	38	100%

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* Per study inclusion criteria, emmetropes desiring near correction were enrolled with plano (defined as -0.50 to +0.50 D) One ineligible subject was enrolled with -0.75 D preoperative CRSE.

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Table 3 summarizes the preoperative refractive parameters for the eyes treated for near. The majority of eyes (92 eyes, 61%) treated for near had a CRSE (cycloplegic refraction spherical equivalent) between 0.00 (plano) and 0.99 D. Of the population of 150 eyes treated for near, 41 eyes (27%) presented with CRSE between 1.00 and 2.00 D and 17 eyes (11%) had a myopic CRSE at baseline (-0.50 to -0.125 D), since a plano refraction was defined as +0.50 to -0.50 D in the protocol. One eye was enrolled with -0.75 D preoperative CRSE and no near eyes exceeded the protocol requirement of $\leq$ 0.75 D of cylinder in the cycloplegic refraction.

ACCOUNTABILITY

Table 4
Accountability
Eyes Treated for Near

	Month 1		Month 3		Month 6		Month 9		Month 12	
Available for Analysis	145/150	97%	148/150	99%	146/150	97%	94/150	63%	77/150	51%
Discontinued*	0/150	0%	0/150	0%	2/150	1%	4/150	3%	9/150	6%
Missed Visit	5/150	3%	2/150	1%	4/150	3%	3/150	2%	3/150	2%
Not yet eligible for interval	0/150	0%	0/150	0%	0/150	0%	53/150	35%	70/150	47%
Lost to Follow-up	0/150	0%	0/150	0%	0/150	0%	0/150	0%	1/150	1%
Accountability	145/150	97%	148/150	99%	146/150	97%	94/97	97%	77/80	96%

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* 1 eye discontinued due to inability of patient to continue in study; 1 eye discontinued due to an adverse event (multiple sclerosis); 1 eye discontinued for retreatment with PRK; 12 eyes discontinued for CK retreatment as per study protocol. See Table 16.2.

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As shown in Table 4, accountability was excellent for eyes treated for near. Of the total study population of 150 eyes treated for near, 145 eyes (97%) were available for analysis at 1 month, 148 eyes (99%) were available at 3 months, 146 eyes (97%) at 6 months, 94 eyes (63%) at 9 months and 77 eyes (51%) at 12 months. No more than 3% of subjects missed a scheduled follow-up visit at each interval resulting in accountability at each visit interval $\geq$ 96%. None of the study subjects were lost-to-follow-up except for one eye at 12 months.

SAFETY AND EFFICACY RESULTS

A. Summary of Key Safety and Efficacy Variables

Table 5
Summary of Key Safety and Efficacy Variables
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Month 1		Month 3		Month 6		Month 9		Month 12	
Efficacy Variables -- Eyes Treated for Near (Full Correction)*										
UCVA-N J1+ or better	22/78	28%	20/81	25%	19/81	23%	16/64	25%	7/53	13%
UCVA-N J1 or better	46/78	59%	44/81	54%	41/81	51%	31/64	48%	20/53	38%
UCVA-N J2 or better	64/78	82%	62/81	77%	59/81	73%	48/64	75%	37/53	70%
UCVA-N J3 or better	71/78	91%	71/81	88%	67/81	83%	54/64	84%	43/53	81%
UCVA-N J5 or better	76/78	97%	79/81	98%	76/81	94%	59/64	92%	52/53	98%
UCVA-N J7 or better	78/78	100%	81/81	100%	79/81	98%	62/64	97%	53/53	100%
Efficacy Variables -- Eyes Treated for Near*										
MRSE ≤ 0.5 D from Target	55/88	63%	60/91	66%	59/91	65%	50/73	68%	43/62	69%
MRSE ≤ 1.0 D from Target	79/88	90%	82/91	90%	83/91	91%	66/73	90%	58/62	94%
MRSE ≤ 2.0 D from Target	88/88	100%	91/91	100%	91/91	100%	73/73	100%	62/62	100%
Safety Variables -- Eyes Treated for Near										
Loss of > 2 lines BCVA-D	2/90	2%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Loss of ≥ 2 lines BCVA-D	3/90	3%	1/93	1%	2/93	2%	0/74	0%	0/63	0%
BCVA-D worse than 20/40	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Increase > 2 D cylinder	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Preop BCVA-D ≤ 20/20 to >20/25	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Loss of > 2 lines BCVA-N	0/89	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Loss of ≥ 2 lines BCVA-N	0/89	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
BCVA-N worse than J3	0/89	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%

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* Efficacy analyses exclude 3 eyes with a target near correction of > -2.00 D, the maximum allowed in the protocol.

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Key safety and efficacy variables for eyes treated for near are summarized in Table 5. The objective of this study was to evaluate the safety and effectiveness of the CK® procedure to improve near vision (i.e. at 14 inches). However, the study protocol allowed patients and investigators the option to select an intermediate distance target (i.e., computer screen, bookshelf, etc.). This would result in a compromised uncorrected visual acuity when measured at near (i.e. 14 inches). Therefore, uncorrected visual acuity is presented for the cohort of eyes treated for near with intended correction of 1.00 to 2.25 D with full correction. Eyes that underwent only a partial correction for near (n = 14) were excluded from the analysis of uncorrected visual acuity.

Accuracy of the refractive outcome, expressed as the proportion of eyes within 0.50 D and within 1.00 D of the target refraction, is reported for all eyes treated for near with intended correction of 1.00 to 2.25 D (with the exception of three eyes with a target near correction greater than the maximum of -2.00 D allowed in the study protocol). Safety is reported for the entire cohort of eyes treated for near; safety parameters include measures of best-corrected distance visual acuity as well as best corrected near visual acuity.

As shown in Table 5, the proportion of eyes treated for near with a full correction achieving uncorrected visual acuity of J1 (20/25) or better was 59% (46/78) at 1 month, 54% (44/81) at 3 months, 51% (41/81) at 6 months, 48% (31/64) at 9 months, and 38% (20/53) at 12 months. The proportion of eyes treated for near with a full correction achieving uncorrected visual acuity of J3 (20/40) or better was 91% (71/78) at 1 month, 88% (71/81) at 3 months, 83% (67/81) at 6 months, 84% (54/64) at 9 months, and 81% (43/53) at 12 months. Thus, the target for uncorrected near visual acuity of 75% of eyes at J3 (20/40) or better was achieved in this cohort.

The study protocol target of 50% of eyes with accuracy of the refractive outcome within $\pm$ 0.50 D of target was met or approximated at every postoperative interval for the full cohort of eyes treated for near. The percentage of eyes that met this criterion was 63% (55/88) at 1 month, 66% (60/91) at 3 months, 65% (59/91) at 6 months, 68% (50/73) at 9 months, and 69% (43/62) at 12 months. Additionally, the study protocol target of 75% of eyes within $\pm$ 1.00 D of target was met at every postoperative interval. The proportion of eyes treated for near that achieved this level of refractive predictability was 90% (79/88) at 1 month, 90% (82/91) at 3 months, 91% (83/91) at 6 months, 90% (66/73) at 9 months, and 94% (58/62) at 12 months.

All target outcomes for safety were achieved in the population of eyes treated for near. A transient loss of more than 2 lines BCVA-D was reported for 2 eyes (2%) at 1 month and in both eyes this resolved by 3 months. None of the study eyes had distance BCVA worse than 20/40 or induced cylinder of more than 2.00 D at any postoperative visit. Similarly, no eyes with BCVA-D of 20/20 or better at baseline had distance BCVA worse than 20/25 at any postoperative interval.

None of the study eyes demonstrated any compromise in BCVA-N, with no eyes reporting a loss of greater than or equal to two lines and no eyes reported a BCVA-N worse than J3 at any postoperative interval.

Key safety and efficacy variables for eyes treated for near at 6 months stratified by treatment spots applied are summarized in Table 6a. As shown below, uncorrected near acuity of J3 (20/40) or better was achieved by 83% of eyes treated with 16 spots and in 82% of eyes treated with 24 spots.

Table 6a
Summary of Key Safety and Efficacy Variables at Month 6, Stratified by Treatment Spots Applied
Eyes Treated for Near with Intended Correction of 1.00 to 2.25D

	16 Spots		24 Spots	
	1.00 - 1.63 D		1.75 - 2.25 D	
Efficacy Variables -- Eyes Treated for Near with Full Correction*				
UCVA-N J1+ or better	9/36	25%	10/44	23%
UCVA-N J1 or better	14/36	39%	26/44	59%
UCVA-N J2 or better	26/36	72%	32/44	73%
UCVA-N J3 or better	30/36	83%	36/44	82%
UCVA-N J5 or better	32/36	89%	43/44	98%
UCVA-N J7 or better	34/36	94%	44/44	100%
Efficacy Variables -- Eyes Treated for Near*				
MRSE ≤ 0.5 D from Target	28/42	67%	31/48	65%
MRSE ≤ 1.0 D from Target	38/42	90%	44/48	92%
MRSE ≤ 2.0 D from Target	42/42	100%	48/48	100%
Safety Variables – Eyes Treated for Near				
Loss of > 2 lines BCVA-D	0/42	0%	0/50	0%
Loss of ≥ 2 lines BCVA-D	0/42	0%	2/50	4%
BCVA-D worse than 20/40	0/42	0%	0/50	0%
Increase > 2 D cylinder	0/42	0%	0/50	0%
Preop BCVA-D ≤ 20/20 to >20/25	0/42	0%	0/50	0%
Loss of > 2 lines BCVA-N	0/42	0%	0/50	0%
Loss of ≥ 2 lines BCVA-N	0/42	0%	0/50	0%
BCVA-N worse than J3	0/42	0%	0/50	0%

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* Efficacy analyses exclude 3 eyes with a target near correction of > -2.00 D, the maximum allowed in the protocol.

Note: Table excludes 1 eye treated intraoperatively for induced cylinder.

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Key safety and efficacy variables for eyes treated for near at 12 months stratified by treatment spots applied are summarized in Table 6b. As shown below, uncorrected near acuity of J3 (20/40) or better was achieved by 89% of eyes treated with 16 spots and in 72% of eyes treated with 24 spots.

Table 6b
Summary of Key Safety and Efficacy Variables at Month 12, Stratified by Treatment Spots Applied
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	16 Spots		24 Spots	
	1.00 - 1.63 D		1.75 - 2.25 D	
Efficacy Variables -- Eyes Treated for Near with Full Correction*				
UCVA-N J1+ or better	6/28	21%	1/25	4%
UCVA-N J1 or better	13/28	46%	7/25	28%
UCVA-N J2 or better	22/28	79%	15/25	60%
UCVA-N J3 or better	25/28	89%	18/25	72%
UCVA-N J5 or better	28/28	100%	24/25	96%
UCVA-N J7 or better	28/28	100%	25/25	100%
Efficacy Variables -- Eyes Treated for Near*				
MRSE ≤ 0.5 D from Target	28/34	82%	15/28	54%
MRSE ≤ 1.0 D from Target	33/34	97%	25/28	89%
MRSE ≤ 2.0 D from Target	34/34	100%	28/28	100%
Safety Variables -- Eyes Treated for Near				
Loss of > 2 lines BCVA-D	0/34	0%	0/29	0%
Loss of ≥ 2 lines BCVA-D	0/34	0%	0/29	0%
BCVA-D worse than 20/40	0/34	0%	0/29	0%
Increase > 2 D cylinder	0/34	0%	0/29	0%
Preop BCVA-D ≤ 20/20 to >20/25	0/34	0%	0/29	0%
Loss of > 2 lines BCVA-N	0/34	0%	0/29	0%
Loss of ≥ 2 lines BCVA-N	0/34	0%	0/29	0%
BCVA-N worse than J3	0/34	0%	0/29	0%

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* Efficacy analyses exclude 3 eyes with a target near correction of > -2.00 D, the maximum allowed in the protocol.

Note: Table excludes 1 eye treated intraoperatively for induced cylinder.

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As shown in Table 6c, the percentage of eyes undercorrected by > 1.00 D stratified by spot pattern at 6 months is 10% for 16 spots and 8% for 24 spots. At 12 months, 3% of eyes treated with 16 spots and 11% of eyes treated with 24 spots were undercorrected by > 1.00 D.

Table 6c
Eyes Undercorrected by > 1.00 D,
Stratified by Treatment Spots Applied
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	16 Spots 1.00 – 1.63 D	24 Spots 1.75 – 2.25 D
6 Months	4/42 10%	4/49 8%
12 Months	1/34 3%	3/28 11%

Table 6d represents the proportion of eyes with near UCVA of J3 (20/40) or better at 6 months, stratified by age and number of treatment spots.

Table 6d
Proportion of Eyes with Near UCVA J3 (20/40) or Better at 6 Months,
Stratified by Age and Treatment Spots Applied
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	≤ 50 years	50 to < 55 years	≥ 55 years	All Eyes
16 spots 1.00 – 1.63 D	11/14 79%	11/12 92%	8/10 80%	30/36 83%
24 spots 1.75 – 2.25 D	14/14 100%	16/22 73%	7/9 78%	37/45 82%
All Eyes	25/28 89%	27/34 79%	15/19 79%	

B. Binocular Outcomes

The improvement in near vision is accomplished through the application of CK® to the non-dominant eye to achieve a myopic endpoint (-1.00 to -2.00 D). Therefore, it is important to assess the impact of intentional anisometropia on binocular vision.

B.1. Binocular Cumulative UCVA - Near

Binocular cumulative uncorrected visual acuity at near for eyes treated for a full correction at near is shown in Table 7. Preoperatively, only 6 of 81 eyes (7%) had binocular near uncorrected visual acuity of J2 (20/30) or better. Postoperatively, this improved to 85% (66/78) at 1 month, 78% (63/81) at 3 months, 81% (66/81) at 6 months, 84% (54/64) at 9 months, and 77% (41/53) at 12 months. A significant improvement was also observed in the proportion of eyes with binocular UCVA at near of J1 (20/25) or better. Preoperatively, only a single patient (1%) had binocular UCVA of J1 (20/25) or better, and this increased postoperatively to 67% at month 1, 67% at month 3, 56% at month 6, 59% at month 9, and 47% at month 12.

Table 7
Binocular Cumulative Uncorrected Visual Acuity - Near
All Subjects Treated for Near with Intended Correction of 1.00 to 2.25 D (Full Correction)

	Preop		Month 1		Month 3		Month 6		Month 9		Month 12	
UCVA-N J1+ or better	0/81	0%	29/78	37%	25/81	31%	23/81	28%	18/64	28%	12/53	23%
UCVA-N J1 or better	1/81	1%	52/78	67%	54/81	67%	45/81	56%	38/64	59%	25/53	47%
UCVA-N J2 or better	6/81	7%	66/78	85%	63/81	78%	66/81	81%	54/64	84%	41/53	77%
UCVA-N J3 or better	12/81	15%	73/78	94%	74/81	91%	73/81	90%	58/64	91%	47/53	89%
UCVA-N J5 or better	30/81	37%	77/78	99%	80/81	99%	78/81	96%	61/64	95%	52/53	98%
UCVA-N J7 or better	51/81	63%	78/78	100%	81/81	100%	80/81	99%	63/64	98%	53/53	100%
UCVA-N J10 or better	69/81	85%	78/78	100%	81/81	100%	80/81	99%	64/64	100%	53/53	100%
UCVA-N J16 or better	80/81	99%	78/78	100%	81/81	100%	81/81	100%	64/64	100%	53/53	100%
Not reported	0/81	0%	0/78	0%	0/81	0%	0/81	0%	0/64	0%	0/53	0%
Total	81/81	100%	78/78	100%	81/81	100%	81/81	100%	64/64	100%	53/53	100%

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Note: Efficacy analyses exclude 3 eyes with a target near correction of > -2.00 D, the maximum allowed in the protocol.

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B.2. Binocular Cumulative UCVA - Distance

Binocular cumulative distance uncorrected visual acuity is shown in Table 8. Preoperatively, 92% of all subjects had uncorrected distance visual acuity of 20/20 or better. Postoperatively, binocular uncorrected distance visual acuity of 20/20 or better was reported for 98% (85/87) of eyes at 1 month, 97% (88/91) at 3 months, 95% (86/91) at 6 months, 99% (72/73) at 9 months, and 97% (60/62) at 12 months. None of the study subjects had binocular distance uncorrected visual acuity worse than 20/32 at any time during the course of the study. This suggests that the near correction did not have an adverse impact on binocular uncorrected distance acuity.

Table 8
Binocular Cumulative Uncorrected Visual Acuity - Distance
All Subjects Treated for Near with Intended Correction of 1.00 to 2.25 D

	Preop		Month 1		Month 3		Month 6		Month 9		Month 12	
UCVA-D 20/20 or better	84/91	92%	85/87	98%	88/91	97%	86/91	95%	72/73	99%	60/62	97%
UCVA-D 20/25 or better	89/91	98%	87/87	100%	90/91	99%	91/91	100%	73/73	100%	61/62	98%
UCVA-D 20/32 or better	90/91	99%	87/87	100%	91/91	100%	91/91	100%	73/73	100%	62/62	100%
UCVA-D 20/40 or better	91/91	100%	87/87	100%	91/91	100%	91/91	100%	73/73	100%	62/62	100%
UCVA-D 20/80 or better	91/91	100%	87/87	100%	91/91	100%	91/91	100%	73/73	100%	62/62	100%
UCVA-D 20/200 or better	91/91	100%	87/87	100%	91/91	100%	91/91	100%	73/73	100%	62/62	100%
Not reported	0/91	0%	1/88	1%	0/91	0%	0/91	0%	0/73	0%	0/62	0%
Total	91/91	100%	87/87	100%	91/91	100%	91/91	100%	73/73	100%	62/62	100%

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Note: Efficacy analyses exclude 3 eyes with a target near correction of > -2.00 D, the maximum allowed in the protocol.

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B.3. Combined Binocular UCVA at Distance and Near

To ensure that study subjects did not experience an improvement in uncorrected near vision with a concurrent compromise in uncorrected distance acuity, the combination of binocular uncorrected near and distance visual acuity is shown in Table 9. Preoperatively, only 15% (12/81) of patients treated presented with uncorrected visual acuity of both 20/32 or better at distance and J3 (20/40) or better at near. Post-CK® treatment, this improved to 94% (72/77) at 1 month, 91% (74/81) at 3 months, 90% (73/81) at 6 months, 91% (58/64) at 9 months, and 89% (47/53) at 12 months. Additionally, while only 1% (1/81) of patients had uncorrected visual acuity of both 20/20 or better acuity at distance and J1 (20/25) or better at near preoperatively, post-CK® treatment, this improved to 65% (50/77) at month 1, 63% (51/81) at month 3, 51% (41/81) at month 6, 59% (38/64) at month 9, and 45% (24/53) at month 12.

Table 9
Combined Binocular Uncorrected Visual Acuity Distance and Near
All Subjects Treated for Near with Intended Correction of 1.00 to 2.25 D (Full Correction)

	Preop		Month 1		Month 3		Month 6		Month 9		Month 12	
20/20 or better and J1 or better	1/81	1%	50/77	65%	51/81	63%	41/81	51%	38/64	59%	24/53	45%
20/25 or better and J2 or better	6/81	7%	65/77	84%	62/81	77%	66/81	81%	54/64	84%	41/53	77%
20/32 or better and J3 or better	12/81	15%	72/77	94%	74/81	91%	73/81	90%	58/64	91%	47/53	89%
20/40 or better and J3 or better	12/81	15%	72/77	94%	74/81	91%	73/81	90%	58/64	91%	47/53	89%
Not reported	0/81	0%	1/78	1%	0/81	0%	0/81	0%	0/64	0%	0/53	0%
Total	81/81	100%	77/77	100%	81/81	100%	81/81	100%	64/64	100%	53/53	100%

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Note: Efficacy analyses exclude 3 eyes with a target near correction of > -2.00 D, the maximum allowed in the protocol.

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C. Induced Manifest Refraction Cylinder

Table 10
Absolute Change in Refractive Cylinder
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

Astigmatism	Month 1		Month 3		Month 6		Month 9		Month 12	
Increase >2.00 D	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Increase 2.00 D	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Increase 1.75 D	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Increase 1.50 D	5/90	6%	1/93	1%	0/93	0%	0/74	0%	0/63	0%
Increase 1.25 D	6/90	7%	8/93	9%	6/93	6%	2/74	3%	1/63	2%
Increase 1.00 D	15/90	17%	7/93	8%	3/93	3%	2/74	3%	4/63	6%
No Change (± 0.75 D)	64/90	71%	77/93	83%	84/93	90%	70/74	95%	58/63	92%
Decrease 1.00 D	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Decrease >1.00 D	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Not Reported	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Total	90/90	100%	93/93	100%	93/93	100%	74/74	100%	63/63	100%

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Table 10 shows the absolute change in refractive cylinder for eyes treated for near. No eyes presented induced cylinder of > 2.00 D at any postoperative interval. Furthermore, there was no change in magnitude of induced cylinder, defined as change ± 0.75 D, in 71% of eyes at 1 month, increasing to 83% at 3 months, 90% at 6 months, 95% at 9 months and 92% at 12 months.

Table 11
Comparison of Eyes with ≥ 1.00 D of Induced Cylinder and Eyes with < 1.00 D Induced Cylinder
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	< 1.00 D Induced Cylinder			≥ 1.00 D Induced Cylinder		
	Month 6	Month 9	Month 12	Month 6	Month 9	Month 12
Loss of > 2 lines BCVA-N	0/84 0%	0/70 0%	0/58 0%	0/9 0%	0/4 0%	0/5 0%
Loss of 2 lines BCVA-N	0/84 0%	0/70 0%	0/58 0%	0/9 0%	0/4 0%	0/5 0%
Loss of 1 line BCVA-N	3/84 4%	1/70 1%	0/58 0%	0/9 0%	0/4 0%	0/5 0%
No Change	67/84 80%	59/70 84%	49/58 84%	5/9 56%	3/4 75%	5/5 100%
Increase of 1 line BCVA-N	13/84 15%	9/70 13%	9/58 16%	3/9 33%	1/4 25%	0/5 0%
Increase of 2 lines BCVA-N	1/84 1%	1/70 1%	0/58 0%	1/9 11%	0/4 0%	0/5 0%
Increase of > 2 lines BCVA-N	0/84 0%	0/70 0%	0/58 0%	0/9 0%	0/4 0%	0/5 0%
UCVA-N J1 or better	42/84 50%	33/70 47%	20/58 34%	4/9 44%	1/4 25%	2/5 40%
UCVA-N J2 or better	58/84 69%	51/70 73%	39/58 67%	8/9 89%	3/4 75%	3/5 60%
UCVA-N J3 or better	66/84 79%	57/70 81%	45/58 78%	9/9 100%	4/4 100%	4/5 80%
UCVA-N J5 or better	77/84 92%	63/70 90%	54/58 93%	9/9 100%	4/4 100%	5/5 100%
UCVA-N J7 or better	81/84 96%	67/70 96%	56/58 97%	9/9 100%	4/4 100%	5/5 100%
UCVA-N						
N	84	70	58	9	4	5
Mean	2.44	2.51	2.74	1.59	1.92	2.40
95% Confidence Interval	1.95,2.93	1.88,3.14	2.07,3.41	1.08,2.10	0.98,2.86	0.93,3.87
Standard Deviation	2.298	2.719	2.619	0.794	0.956	1.673
Median	1.50	2.00	2.00	2.00	2.00	2.00
Range	0.67,10.00	0.67,16.00	0.67,16.00	0.67,3.00	0.67,3.00	1.00,5.00

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To assess the clinical effect of induced cylinder, uncorrected and best corrected visual acuities were compared for eyes with 1.00 D or more of induced cylinder (≥ 1.00 D) versus eyes with less than 1.00 D of induced cylinder (< 1.00 D). As shown in Table 11, there was no loss of 2 lines or of > 2 lines best corrected near acuity at any time over the course of follow-up, from 6 months through 12 months.

The proportion of eyes achieving uncorrected near visual acuity of J3 (20/40) or better at 6 months was higher in the eyes with ≥ 1.00 D, as compared to eyes with <1.00 D induced cylinder, i.e., 100% vs. 79%, respectively. However, given the relatively small number of eyes in the group with ≥ 1.00 D induced cylinder (N=9) and the potential confounding factor of age, which has not been taken into account for this analysis because of the small number of eyes with ≥ 1.00 D induced cylinder, the clinical relevance of this finding has not been established.

Induced cylinder magnitude by vector analysis is presented in Table 12 for eyes treated for near.

Table 12
Induced Cylinder Magnitude by Vector Analysis
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

Induced Astigmatism	Month 6			Month 9			Month 12		
	n/N	%	95% CI	n/N	%	95% CI	n/N	%	95% CI
0.00 to 0.75 D	63/93	68%	0.573-0.771	56/74	76%	0.643-0.849	49/63	78%	0.655-0.873
>0.75 to 1.00 D	13/93	14%	0.077-0.227	11/74	15%	0.077-0.250	7/63	11%	0.046-0.216
>1.00 to 1.25 D	14/93	15%	0.085-0.240	5/74	7%	0.022-0.151	5/63	8%	0.026-0.176
>1.25 to 1.50 D	2/93	2%	0.003-0.076	1/74	1%	0.000-0.073	1/63	2%	0.000-0.085
>1.50 to 1.75 D	0/93	0%	0.000-0.039	1/74	1%	0.000-0.073	1/63	2%	0.000-0.085
>1.75 to 2.00 D	1/93	1%	0.000-0.058	0/74	0%	0.000-0.049	0/63	0%	0.000-0.057
>2.00 to 2.25 D	0/93	0%	0.000-0.039	0/74	0%	0.000-0.049	0/63	0%	0.000-0.057
>2.25 to 2.50 D	0/93	0%	0.000-0.039	0/74	0%	0.000-0.049	0/63	0%	0.000-0.057
>2.50 to 2.75 D	0/93	0%	0.000-0.039	0/74	0%	0.000-0.049	0/63	0%	0.000-0.057
>2.75 to 3.00 D	0/93	0%	0.000-0.039	0/74	0%	0.000-0.049	0/63	0%	0.000-0.057

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As shown in Table 13, the percent of eyes with > 0.75 D of absolute cylinder magnitude was 0% at baseline, 27% at month 6, 19% at month 9 and 20% at month 12. Additionally, the percent of eyes with > 1.00 D of absolute cylinder magnitude was 0% at baseline, 16% at month 6, 11% at month 9 and 10% at month 12.

Table 13
Absolute Cylinder Magnitude
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

Astigmatism	Preoperative			Month 6			Month 9			Month 12		
	n/N	%	95% CI	n/N	%	95% CI	n/N	%	95% CI	n/N	%	95% CI
0.00 to 0.75 D	94/94	100%	0.962-1.000	68/93	73%	0.629-0.818	60/74	81%	0.703-0.893	51/63	81%	0.691-0.898
>0.75 to 1.00 D	0/94	0%	0.000-0.038	10/93	11%	0.053-0.189	6/74	8%	0.030-0.168	6/63	10%	0.036-0.196
>1.00 to 1.25 D	0/94	0%	0.000-0.038	12/93	13%	0.068-0.215	6/74	8%	0.030-0.168	3/63	5%	0.010-0.133
>1.25 to 1.50 D	0/94	0%	0.000-0.038	2/93	2%	0.003-0.076	2/74	3%	0.003-0.094	2/63	3%	0.004-0.110
>1.50 to 1.75 D	0/94	0%	0.000-0.038	1/93	1%	0.000-0.058	0/74	0%	0.000-0.049	0/63	0%	0.000-0.057
>1.75 to 2.00 D	0/94	0%	0.000-0.038	0/93	0%	0.000-0.039	0/74	0%	0.000-0.049	1/63	2%	0.000-0.085
>2.00 to 2.25 D	0/94	0%	0.000-0.038	0/93	0%	0.000-0.039	0/74	0%	0.000-0.049	0/63	0%	0.000-0.057
>2.25 to 2.50 D	0/94	0%	0.000-0.038	0/93	0%	0.000-0.039	0/74	0%	0.000-0.049	0/63	0%	0.000-0.057
>2.50 to 2.75 D	0/94	0%	0.000-0.038	0/93	0%	0.000-0.039	0/74	0%	0.000-0.049	0/63	0%	0.000-0.057
>2.75 to 3.00 D	0/94	0%	0.000-0.038	0/93	0%	0.000-0.039	0/74	0%	0.000-0.049	0/63	0%	0.000-0.057

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As shown in Table 14, when cylinder is present, axis shift is probable and the precise direction of cylinder axis shift is not predictable. The stability of cylinder axis has not been determined.

Table 14
Absolute Shift in Axis
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

Induced Shift	Month 6			Month 9			Month 12		
	n/N	%	95% CI	n/N	%	95% CI	n/N	%	95% CI
0°	20/93	22%	0.137-0.312	17/74	23%	0.140-0.342	16/63	0%	0.153-0.379
1° to 5°	7/93	8%	0.031-0.149	9/74	12%	0.057-0.218	7/63	50%	0.046-0.216
6° to 10°	8/93	9%	0.038-0.162	5/74	7%	0.022-0.151	7/63	0%	0.046-0.216
11° to 15°	11/93	12%	0.061-0.202	5/74	7%	0.022-0.151	3/63	0%	0.010-0.133
16° to 20°	2/93	2%	0.003-0.076	3/74	4%	0.008-0.114	4/63	0%	0.018-0.155
21° to 25°	4/93	4%	0.012-0.106	1/74	1%	0.000-0.073	4/63	0%	0.018-0.155
26° to 30°	1/93	1%	0.000-0.058	2/74	3%	0.003-0.094	1/63	50%	0.000-0.085
31° to 35°	6/93	6%	0.024-0.135	3/74	4%	0.008-0.114	0/63	0%	0.000-0.057
36° to 40°	3/93	3%	0.007-0.091	5/74	7%	0.022-0.151	2/63	0%	0.004-0.110
41° to 45°	3/93	3%	0.007-0.091	1/74	1%	0.000-0.073	2/63	0%	0.004-0.110
46° to 50°	2/93	2%	0.003-0.076	4/74	5%	0.015-0.133	3/63	0%	0.010-0.133
51° to 55°	2/93	2%	0.003-0.076	2/74	3%	0.003-0.094	1/63	0%	0.000-0.085
56° to 60°	5/93	5%	0.018-0.121	2/74	3%	0.003-0.094	2/63	0%	0.004-0.110
61° to 65°	1/93	1%	0.000-0.058	3/74	4%	0.008-0.114	3/63	0%	0.010-0.133
66° to 70°	1/93	1%	0.000-0.058	2/74	3%	0.003-0.094	1/63	0%	0.000-0.085
71° to 75°	4/93	4%	0.012-0.106	2/74	3%	0.003-0.094	2/63	0%	0.004-0.110
76° to 80°	6/93	6%	0.024-0.135	3/74	4%	0.008-0.114	1/63	0%	0.000-0.085
81° to 85°	3/93	3%	0.007-0.091	2/74	3%	0.003-0.094	1/63	0%	0.000-0.085
86° to 90°	4/93	4%	0.012-0.106	3/74	4%	0.008-0.114	3/63	0%	0.010-0.133

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D. Change in Best Spectacle Corrected Visual Acuity

Table 15
Change in Best Spectacle Corrected Visual Acuity - Near
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Month 1		Month 3		Month 6		Month 9		Month 12	
Decrease > 2 lines	0/89	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Decrease 2 lines	0/89	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Decrease 1 line	11/89	12%	7/93	8%	3/93	3%	1/74	1%	0/63	0%
No Change	65/89	73%	69/93	74%	72/93	77%	62/74	84%	54/63	86%
Increase 1 line	11/89	12%	15/93	16%	16/93	17%	10/74	14%	9/63	14%
Increase 2 lines	2/89	2%	2/93	2%	2/93	2%	1/74	1%	0/63	0%
Increase > 2 lines	0/89	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Not reported	1/90	1%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Total	89/89	100%	93/93	100%	93/93	100%	74/74	100%	63/63	100%

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Table 15 shows change in BCVA at near for eyes treated for near. Nearly all eyes, i.e., more than 95%, had either no change in BCVA-N or a change of only one line (either increase or decrease). No eyes reported a loss of 2 or more lines of BCVA-N at any postoperative interval. Thus, the safety target of < 5% loss of 2 lines or more BCVA at near was achieved for all eyes treated for near.

Table 16
Change in Best Spectacle Corrected Visual Acuity - Distance
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Month 1		Month 3		Month 6		Month 9		Month 12	
Decrease > 2 lines	2/90	2%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Decrease 2 lines	1/90	1%	1/93	1%	2/93	2%	0/74	0%	0/63	0%
Decrease 1 line	33/90	37%	14/93	15%	12/93	13%	6/74	8%	5/63	8%
No Change	38/90	42%	54/93	58%	52/93	56%	42/74	57%	33/63	52%
Increase 1 line	16/90	18%	23/93	25%	24/93	26%	24/74	32%	23/63	37%
Increase 2 lines	0/90	0%	1/93	1%	2/93	2%	2/74	3%	2/63	3%
Increase > 2 lines	0/90	0%	0/93	0%	1/93	1%	0/74	0%	0/63	0%
Not reported	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Total	90/90	100%	93/93	100%	93/93	100%	74/74	100%	63/63	100%

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Table 16 shows change in BCVA-D for eyes treated for near. Ninety-seven percent of eyes at month 1 had a change in BCVA-D of no more than a single line (gain or loss), and this remained relatively constant over the course of follow-up through 12 months. Thus, the safety target of < 5% loss of 2 lines or more BCVA at near was met for all eyes treated for near.

E. Change in Manifest Refraction Over Time

Table 17a
Stability of Manifest Refraction through Month 12 (Eyes with Consecutive Visits)
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months	Between 9 and 12 Months
Change in MRSE ≤ 0.50 D	70/88 80%	78/91 86%	72/73 99%	59/62 95%
Change in MRSE ≤ 0.75 D	80/88 91%	86/91 95%	72/73 99%	60/62 97%
Change in MRSE ≤ 1.00 D	83/88 94%	91/91 100%	73/73 100%	61/62 98%
Change in MRSE/Month (Paired Differences in D)				
Mean	0.06	0.04	0.04	0.03
95% Confidence Interval	0.00,0.12	0.02,0.06	0.02,0.06	0.01,0.05
Standard Deviation	0.241	0.125	0.081	0.098
Change in MRSE (Paired Differences in D)				
Mean	0.12	0.13	0.11	0.10
95% Confidence Interval	0.02,0.22	0.05,0.21	0.05,0.17	0.02,0.18
Standard Deviation	0.482	0.375	0.243	0.293

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Note: Efficacy analyses exclude 3 eyes with a target near correction of > -2.00 D, the maximum allowed in the protocol.

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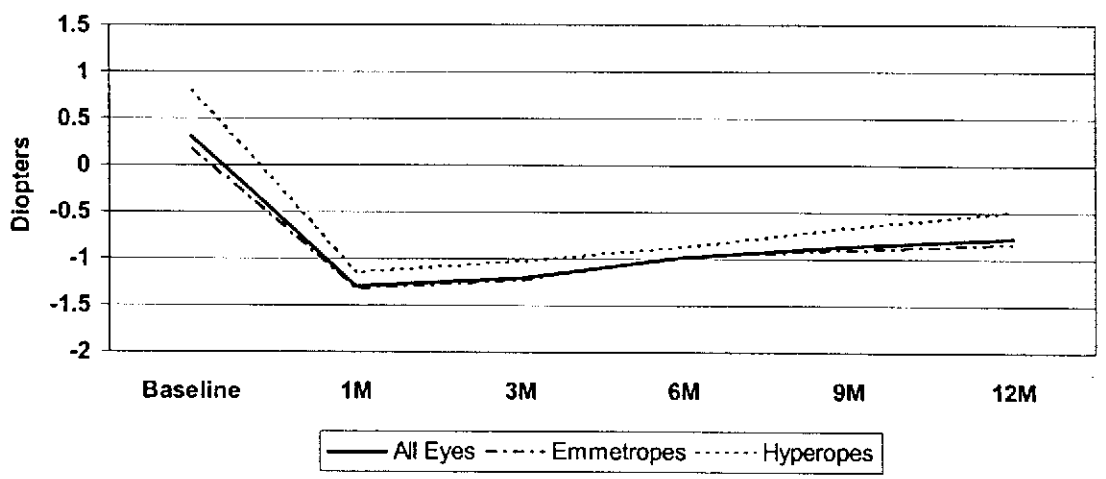
Stability of manifest refraction for groups of eyes with consecutive visits (i.e., 1 and 3 months, 3 and 6 months, 6 and 9 months, and 9 and 12 months) is shown in Table 17a. For these eyes, the change in MRSE of ≤ 1.00 D was 94% between 1 and 3 months, 100% between 3 and 6 months, 100% between 6 and 9 months, and 98% between 9 and 12 months. A large majority of eyes had a change in MRSE of ≤ 0.50 D; with 80% between 1 and 3 months, 86% between 3 and 6 months, 99% between 6 and 9 months, and 95% between 9 and 12 months.

As demonstrated in the clinical trial, 87% (54/62) of eyes maintained their 6 month refractive effect at 12 months within ± 0.50 D of the MRSE measured at 6 months postoperative. When stratified by refractive status at baseline, 89% (41/46) of emmetropic eyes maintained their initial refractive effect at 12 months, while 80% (12/15) of hyperopic eyes maintained their initial refractive effect at 12 months.

Depending on subject age and preoperative accommodative amplitude, as well as postoperative refractive drift, post-op near vision outcome may change over time, with eventual need for spectacle or contact lens correction or retreatment. A total of 10 eyes treated within the approved treatment range (1.00 to 2.25 D) underwent retreatment. In the 7 eyes with at least 6 month follow-up, improvement in uncorrected near vision was achieved in 3 eyes, no improvement in uncorrected near vision was reported in 3 eyes, and a decrease in uncorrected near vision was reported for 1 eye. Only 1 of the 7 eyes reported subjective satisfaction with visual outcome at their last visit. The safety and effectiveness of retreatments is not known and may not be clinically acceptable.

As shown below, mean MRSE over time is depicted graphically for all eyes treated for near with intended correction of 1.00 to 2.25 D. This information is also shown stratified by baseline status (i.e. emmetrope and hyperope).

Mean MRSE Over Time
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D



Mean difference in MRSE stratified by spot pattern for all eyes treated for near with intended correction of 1.00 to 2.25 D is shown below in Table 17b.

Table 17b
Mean Difference in MRSE*
Stratified by Spot Pattern (Consecutive Visits)
All Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

		Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months	Between 9 and 12 Months
16 Spots 1.00 – 1.63 D	N	40	42	40	34
	Mean	0.05	0.06	0.01	0.02
	95% CI	-0.01, 0.11	0.02, 0.10	-0.01, 0.03	0.00, 0.04
	SD	0.191	0.111	0.075	0.068
24 Spots 1.75 – 2.25 D	N	47	48	33	28
	Mean	0.06	0.02	0.06	0.06
	95% CI	-0.02, 0.14	-0.02, 0.06	0.04, 0.08	0.02, 0.10
	SD	0.270	0.136	0.080	0.122

* The duration of the initial refractive effect is not known.

VI. PATIENT SATISFACTION AND PATIENT SYMPTOMS

PATIENT SATISFACTION

Subjects were asked to rate their quality of vision as compared to the quality of vision before the Conductive Keratoplasty® (CK®) procedure (Table 18). Quality of vision was graded on a scale of extreme improvement, marked improvement, moderate improvement, slight improvement or no improvement.

Table 18
Quality of Vision
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Month 1		Month 3		Month 6		Month 9		Month 12	
Extreme Improvement	32/89	36%	40/92	43%	40/93	43%	28/74	38%	24/62	39%
Marked Improvement	36/89	40%	32/92	35%	30/93	32%	23/74	31%	26/62	42%
Moderate Improvement	13/89	15%	15/92	16%	13/93	14%	17/74	23%	9/62	15%
Slight Improvement	6/89	7%	4/92	4%	7/93	8%	3/74	4%	2/62	3%
No Improvement	2/89	2%	1/92	1%	3/93	3%	3/74	4%	1/62	2%
Not Reported	1/90	1%	1/93	1%	0/93	0%	0/74	0%	1/63	2%
Total	89/89	100%	92/92	100%	93/93	100%	74/74	100%	62/62	100%

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The majority of patients reported experiencing moderate, marked or extreme improvement in quality of vision, ranging from 89% to 95% over the postoperative period from one to twelve months.

As shown below in Table 19, overall patient satisfaction was assessed on a patient survey at 1, 3, 6, 9, and 12 months post-treatment using a 5-point grading scale from very satisfied to very dissatisfied.

Table 19
Patient Satisfaction
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Month 1		Month 3		Month 6		Month 9		Month 12	
Very Satisfied	49/90	54%	54/92	59%	48/93	52%	38/74	51%	35/62	56%
Satisfied	29/90	32%	25/92	27%	26/93	28%	21/74	28%	17/62	27%
Neutral	7/90	8%	11/92	12%	16/93	17%	12/74	16%	7/62	11%
Dissatisfied	5/90	6%	2/92	2%	3/93	3%	3/74	4%	3/62	5%
Very Dissatisfied	0/90	0%	0/92	0%	0/93	0%	0/74	0%	0/62	0%
Not Reported	0/90	0%	1/93	1%	0/93	0%	0/74	0%	1/63	2%
Total	90/90	100%	92/92	100%	93/93	100%	74/74	100%	62/62	100%

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Over the postoperative course of follow-up, 79% to 86% of patients reported being satisfied to very satisfied.

Table 20
Quality of Depth Perception
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Preop		Month 1		Month 3		Month 6		Month 9		Month 12	
Depth Perception*												
Excellent	15/81	19%	11/90	12%	25/91	27%	22/93	24%	15/73	21%	12/61	20%
Very Good	30/81	37%	34/90	38%	26/91	29%	39/93	42%	28/73	38%	24/61	39%
Good	31/81	38%	38/90	42%	34/91	37%	24/93	26%	25/73	34%	21/61	34%
Fair	4/81	5%	7/90	8%	6/91	7%	6/93	6%	5/73	7%	4/61	7%
Poor	1/81	1%	0/90	0%	0/91	0%	2/93	2%	0/73	0%	0/61	0%
Not Reported	13/94	14%	0/90	0%	2/93	2%	0/93	0%	1/74	1%	2/63	3%
Total	81/81	100%	90/90	100%	91/91	100%	93/93	100%	73/73	100%	61/61	100%

* Preoperative depth perception was assessed wearing monovision contact lenses.

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As shown in Table 20, quality of depth perception for eyes treated for near was graded by study participants using a scale of excellent, very good, good, fair and poor. Overall, there was no significant change from baseline (depth perception wearing preoperative monovision contact lenses) in the proportion of patients describing depth perception as excellent, very good or good. Postoperatively, between 91% and 93% of study participants rated depth perception in these three categories.

Table 21a
Spectacle Dependence for Near Vision
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Month 1		Month 3		Month 6		Month 9		Month 12	
Do you wear spectacles or contact lenses for near vision in your treated eye?	28/90	31%	27/93	29%	36/93	39%	32/74	43%	33/63	52%
All near activities	3/90	3%	4/93	4%	14/93	15%	12/74	16%	8/63	13%
Working on computer*	13/90	14%	10/93	11%	14/93	15%	16/74	22%	10/63	16%
Reading	28/90	31%	26/93	28%	34/93	37%	30/74	41%	33/63	52%

* Monitor distance and screen contrast not standardized.

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The questionnaire used during the study asked a single question regarding use of spectacles or contact lenses for near vision, the results of which are shown above in Table 21a. In response to this single question, i.e., "do you wear spectacles or contact lenses for near in your treated eye," at 6 months, 39% of patients responded in the affirmative. However, only 15% of patients reported wearing correction for all near activities, while 15% reported using correction for working on a computer, and 37% used correction for reading.

Even in subjects who achieve good UCVA-N post-operatively, some use of spectacles is likely to be required for certain tasks. The goal of monovision is to improve functional near vision. However, complete independence from spectacles for all near tasks is not a goal of this procedure and is unrealistic. The challenge of very fine point near tasks may be beyond the capability of this procedure, and perhaps of any monovision technique. Spectacle correction over monovision may be required for specific near point tasks, such as reading fine print or demanding visual tasks (i.e. reading which requires detail and persists for a long duration) where binocular near vision may be preferred.

Table 21b
Spectacle Dependence for Distance Vision
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Month 1		Month 3		Month 6		Month 9		Month 12	
Do you wear spectacles or contact lenses for distance vision in your treated eye?	0/90	0%	2/93	2%	2/93	2%	3/74	4%	2/63	3%
Whenever driving	0/90	0%	0/93	0%	1/93	1%	2/74	3%	1/63	2%
Night driving only	0/90	0%	2/93	2%	2/93	2%	1/74	1%	1/63	2%
Watching TV or movies	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Sporting events/activities only	0/90	0%	0/93	0%	0/93	0%	0/74	0%	1/63	2%
All distance activities (full time)	0/90	0%	0/93	0%	0/93	0%	0/74	0%	1/63	2%

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As shown in Table 21b, over the course of the study, i.e., from 3 months through 12 months, only 1% to 3% of subjects reported needing spectacle or contact lens correction for driving (including night driving), watching TV or movies, watching or participating in sporting events/activities, or all distance activities. Thus, the monovision corrections performed in the PMA clinical trial did not compromise distance acuity, as evidenced by the results of this questionnaire and further supported by the good binocular uncorrected distance acuities reported for the study population.

PATIENT SYMPTOMS

Subjects were asked to complete a questionnaire that allowed them to report any symptoms or complaints they had regarding their vision or ocular comfort following the procedure. Table 22 summarizes the change in patient symptoms from baseline to months 6, 9 and 12 in eyes treated for near. At 6 months, symptoms which became significantly worse were gritty, scratchy, or sandy feeling (1 eye, 1%), glare (1 eye, 1%), halos (1 eye, 1%), blurred vision (2 eyes, 2%), double vision (1 eye, 1%), fluctuation of vision (1 eye, 1%), variation of vision in bright light (2 eyes, 2%), variation of vision in normal light (1 eye, 1%), variation of vision in dim light (2 eyes, 2%), night driving vision problems (3 eyes, 3%) and other symptom (1 eye, 1%).

Table 22
Change in Patient Symptoms from Preoperative to 6, 9, and 12 Months
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Month 6						Month 9						Month 12					
	Unchanged or Better		Worse		Significantly Worse		Unchanged or Better		Worse		Significantly Worse		Unchanged or Better		Worse		Significantly Worse	
	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%
Light Sensitivity	87/90	97	3/90	3	0/90	0	73/73	100	0/73	0	0/73	0	58/61	95	3/61	5	0/61	0
Headache	89/90	99	1/90	1	0/90	0	70/72	97	2/72	3	0/72	0	60/60	100	0/60	0	0/60	0
Pain	89/90	99	1/90	1	0/90	0	72/72	100	0/72	0	0/72	0	60/60	100	0/60	0	0/60	0
Redness	90/91	99	1/91	1	0/91	0	73/73	100	0/73	0	0/73	0	61/61	100	0/61	0	0/61	0
Dryness	88/92	96	4/92	4	0/92	0	69/74	93	4/74	5	1/74	1	61/62	98	1/62	2	0/62	0
Excessive Tearing	91/91	100	0/91	0	0/91	0	73/73	100	0/73	0	0/73	0	61/61	100	0/61	0	0/61	0
Burning	90/91	99	1/91	1	0/91	0	73/73	100	0/73	0	0/73	0	61/61	100	0/61	0	0/61	0
Gritty, Scratchy, or Sandy Feeling	90/91	99	0/91	0	1/91	1	72/73	99	1/73	1	0/73	0	60/61	98	1/61	2	0/61	0
Glare	85/91	93	5/91	5	1/91	1	67/73	92	5/73	7	1/73	1	57/61	93	2/61	3	2/61	3
Halos	81/91	89	9/91	10	1/91	1	67/73	92	5/73	7	1/73	1	56/61	92	3/61	5	2/61	3
Blurred Vision	81/91	89	8/91	9	2/91	2	67/73	92	6/73	8	0/73	0	55/61	90	4/61	7	2/61	3
Double Vision	86/91	95	4/91	4	1/91	1	68/73	93	5/73	7	0/73	0	54/61	89	6/61	10	1/61	2
Fluctuation of Vision	82/91	90	8/91	9	1/91	1	70/73	96	3/73	4	0/73	0	56/61	92	4/61	7	1/61	2
Variation of Vision in Bright Light	85/91	93	4/91	4	2/91	2	69/73	95	3/73	4	1/73	1	58/61	95	3/61	5	0/61	0
Variation of Vision in Normal Light	88/90	98	1/90	1	1/90	1	71/72	99	1/72	1	0/72	0	56/60	93	3/60	5	1/60	2
Variation of Vision in Dim Light	86/90	96	2/90	2	2/90	2	69/72	96	3/72	4	0/72	0	54/60	90	3/60	5	3/60	5
Night Driving Vision Problems	87/92	95	2/92	2	3/92	3	70/74	95	2/74	3	2/74	3	58/62	94	1/62	2	3/62	5
Other Symptom	81/85	95	3/85	4	1/85	1	67/68	99	0/68	0	1/68	1	55/55	100	0/55	0	0/55	0

Note: Unchanged or Better = 1 point increase, no change, or any decrease; Worse = 2 point increase, Significantly Worse = 3 point increase or greater.

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Table 23 shows the incidence of "none," "mild," "moderate," "marked," and "very severe" for each symptom at baseline, 1 month, 6 months, and 12 months postoperative. While a clinically significant increase in postoperative symptoms was observed, the majority changed from "none" to "mild". The symptoms that reported a significant increase (>5%) from preoperative to 6 months or beyond in the "moderate" category are glare, *halos*, double vision, fluctuation of vision and variation of vision in dim light.

Table 23
Patient Symptoms

Subjective Responses	None	Mild	Moderate	Marked	Very Severe
Light Sensitivity					
Preop	81%	15%	3%	1%	0%
Month 1	56%	31%	10%	2%	1%
Month 6	71%	23%	6%	0%	0%
Month 12	76%	19%	5%	0%	0%
Headaches					
Preop	92%	5%	0%	1%	1%
Month 1	94%	4%	1%	0%	0%
Month 6	94%	5%	1%	0%	0%
Month 12	94%	5%	2%	0%	0%
Pain					
Preop	98%	2%	0%	0%	0%
Month 1	93%	6%	1%	0%	0%
Month 6	97%	2%	1%	0%	0%
Month 12	100%	0%	0%	0%	0%
Redness					
Preop	94%	6%	0%	0%	0%
Month 1	92%	7%	1%	0%	0%
Month 6	96%	3%	1%	0%	0%
Month 12	97%	3%	0%	0%	0%
Dryness					
Preop	84%	14%	1%	0%	1%
Month 1	67%	24%	7%	1%	1%
Month 6	71%	24%	5%	0%	0%
Month 12	79%	19%	2%	0%	0%

Table 23
Patient Symptoms (continued)

Subjective Responses	None	Mild	Moderate	Marked	Very Severe
Excessive Tearing					
Preop	96%	2%	2%	0%	0%
Month 1	93%	7%	0%	0%	0%
Month 6	96%	3%	0%	1%	0%
Month 12	97%	3%	0%	0%	0%
Burning					
Preop	97%	1%	2%	0%	0%
Month 1	92%	6%	1%	1%	0%
Month 6	92%	6%	1%	0%	0%
Month 12	100%	0%	0%	0%	0%
Gritty, Scratchy or Sandy Feeling					
Preop	92%	6%	1%	0%	0%
Month 1	82%	13%	3%	1%	0%
Month 6	88%	11%	0%	1%	0%
Month 12	97%	2%	2%	0%	0%
Glare					
Preop	94%	5%	1%	0%	0%
Month 1	64%	23%	9%	3%	0%
Month 6	65%	27%	8%	1%	0%
Month 12	73%	21%	3%	3%	0%
Halos					
Preop	96%	3%	1%	0%	0%
Month 1	69%	17%	9%	3%	2%
Month 6	72%	15%	12%	1%	0%
Month 12	74%	16%	6%	3%	0%
Blurred Vision					
Preop	81%	12%	6%	0%	1%
Month 1	47%	32%	13%	7%	1%
Month 6	59%	27%	11%	3%	0%
Month 12	68%	19%	8%	5%	0%
Double Vision					
Preop	97%	3%	0%	0%	0%
Month 1	77%	13%	6%	4%	0%
Month 6	83%	12%	4%	0%	1%
Month 12	81%	8%	10%	2%	0%

Table 23
Patient Symptoms (continued)

Subjective Responses	None	Mild	Moderate	Marked	Very Severe
Fluctuation of Vision					
Preop	94%	4%	2%	0%	0%
Month 1	51%	33%	12%	3%	0%
Month 6	65%	25%	10%	1%	0%
Month 12	69%	23%	6%	2%	0%
Variation in Vision in Bright Light					
Preop	86%	12%	2%	0%	0%
Month 1	63%	24%	9%	3%	0%
Month 6	70%	23%	2%	5%	0%
Month 12	84%	11%	3%	2%	0%
Variation in Vision in Normal Light					
Preop	95%	4%	1%	0%	0%
Month 1	70%	20%	9%	1%	0%
Month 6	75%	23%	1%	1%	0%
Month 12	81%	13%	5%	2%	0%
Variation in Vision in Dim Light					
Preop	86%	10%	3%	1%	0%
Month 1	61%	27%	9%	3%	0%
Month 6	62%	28%	5%	4%	0%
Month 12	65%	21%	10%	3%	2%
Night Driving Vision Problems					
Preop	86%	12%	2%	0%	0%
Month 1	61%	22%	10%	6%	1%
Month 6	66%	27%	4%	3%	0%
Month 12	82%	10%	3%	3%	2%
Other Symptom					
Preop	100%	0%	0%	0%	0%
Month 1	97%	0%	1%	2%	0%
Month 6	95%	1%	3%	1%	0%
Month 12	100%	0%	0%	0%	0%